

**REMARKS**

This communication is submitted in response to the Examiner's Office Action dated March 27, 2001. Claims 1-28 are pending in the case. In the Office Action, the Examiner rejected claims 8, 10, 11, and 16 under 35 U.S.C. § 112, second paragraph; the Examiner rejected claims 1-3, 5-9, 17-19, 22, 25, and 26 under 35 U.S.C. § 102(b) in view of U.S. Patent No. 5,683,423 to Post ("Post"); the Examiner rejected claims 1-12, 14, 17, and 19-28 under 35 U.S.C. § 102(e) in view of U.S. Patent No. 6,141,584 to Rockwell et al. ("Rockwell"); the Examiner rejected claims 13, 15, and 16 under 35 U.S.C. § 103(a) in view of Rockwell modified by U.S. Patent No. 5,879,374 to Powers et al. ("Powers"); and the Examiner rejected claim 18 under 35 U.S.C. § 103(a) in view of Rockwell modified by U.S. Patent No. 5,345,552 to Brown ("Brown").

**Applicant-Initiated Amendments**

The Applicants have made minor amendments to the application as a result of the careful review in response to the Examiner's Office Action. Specifically, the Applicants have amended claims 6, 15, and 16 to more clearly claim the invention. In claim 6, "the" was deleted to obviate any potential argument of a lack of antecedent basis. In claims 15 and 16, language was inserted to state that the replaying is optional prior to reciting "the replaying option." In claim 15, "instrument" was replaced with "defibrillator" to provide for consistent terminology. In claim 16, "the" was replaced with "a" to obviate any potential argument of a lack of antecedent basis, and "device" was replaced with "defibrillator" to provide for consistent terminology.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

In paragraph 1 of the Office Action, the Examiner rejected claims 8, 10, 11, and 16 as being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicants regard as the invention.

The Examiner rejected claims 10, 11, and 16 as lacking antecedent basis. Although the Examiner did not state her reasons for the rejection of claim 8, it appears that the Examiner also rejected claim 8 due to a lack of antecedent basis. The Applicants have amended the claims to overcome the Examiner's rejections. Therefore, the Examiner's rejections under 35 U.S.C. 112, second paragraph, of claims 8, 10, 11, and 16 are believed to be overcome.

Claim Rejections Under 35 U.S.C. § 102

In paragraph 3 of the Office Action, the Examiner rejected claims 1-3, 5-9, 17-19, 22, 25, and 26 as being anticipated by Post. In paragraph 4 of the Office Action, the Examiner rejected claims 1-12, 14, 17, and 19-28 as being anticipated by Rockwell.

Post discloses a defibrillator that can record audio data and a short duration (e.g., 15 seconds) of ECG data before and after an event marked by the defibrillator user (see column 3 lines 19-24). The ECG data can subsequently be printed on a thermal printer for review. In contrast to Post, the present application discloses and claims a defibrillator having multiple modes of operation. A first mode is the active monitoring/therapy operation mode, in which the defibrillator is used to monitor a patient and deliver therapeutic impulses. A second mode is the incident review mode, in which the defibrillator is used to review previously recorded ECG information. While in the incident review mode, the therapy operation (i.e., the ability

to deliver a therapeutic shock) is disabled; the monitoring operation (i.e., monitoring the patient's ECG signals) may or may not be disabled. (See the application at page 7 lines 12-29.) A second or later responder may review the patient's ECG history on the device screen and while the defibrillator is still connected to the patient. (See the application at pages 3-4.) This type of incident review allows a subsequent, skilled caregiver to quickly review the treatment history, assess the patient's condition, and determine a future therapeutic regimen. This type of incident review is not disclosed in Post. There is no provision in Post for review of recorded ECG data on the defibrillator itself, as is required by the amended claims. Therefore, Post does not anticipate the claims.

Rockwell discloses a defibrillator that includes a wireless communications network that allows for communications between the defibrillator and a host computer for incident report generation. The defibrillator includes a screen that may display "text such as user prompts and graphics such as ECG waveforms" (column 7 lines 29-30). The patient's ECG history may be recorded and transferred to another defibrillator, where it can be printed out for review (column 8 lines 41-52). Alternatively, the patient's ECG history may be downloaded to a portable printer for print out and review (column 8 lines 55-59). However, like Post, there is no provision in Rockwell for review of recorded ECG data on the defibrillator itself, as is required by the amended claims. Therefore, Rockwell does not anticipate the claims.

In view of the foregoing, all of the Examiner's rejections under 35 U.S.C. § 102 to claims 1-12, 14, and 17-28 are believed to be overcome.

Claim Rejections Under 35 U.S.C. § 103

In paragraph 6 of the Office Action, the Examiner rejected claims 13, 15, and 16 as being unpatentable over Rockwell in view of Powers. In paragraph 7 of the Office Action, the Examiner rejected claim 18 as being unpatentable over Rockwell in view of Brown.

As discussed above, Rockwell does not disclose review on the defibrillator itself of previously recorded ECG history. Powers discloses a defibrillator that can perform a variety of self-tests. However, Powers does not disclose any review of a patient's ECG history. Thus, the combination of Rockwell and Powers does not render the claims obvious.

The Examiner states on page 5 of the Office Action that in view of the self-test function that is initiated upon insertion of a battery into the Powers defibrillator, it would have been obvious to activate an incident review mode upon insertion of a battery into the Rockwell defibrillator. The Applicants respectfully traverse this inference. First, there is no disclosure in Rockwell of an incident review mode as the term is used in the present application (see the above discussion regarding Post). Second, no suggestion or motivation is provided for modifying the Powers reference from initiation of a self-test to initiation of incident review. The Examiner states that "[i]t is an obvious design choice that the insertion of the battery could also activate the incident review mode and/or initiate an offer to replay the recorded data." (Office Action at page 5.) The basis for this statement is unclear. The fact that one defibrillator performs a specific function upon insertion of a battery does not render obvious every other function initiated upon insertion of a battery. Nowhere in the cited references is there seen any disclosure of a defibrillator with an incident review

mode as disclosed and claimed in the present application. Thus, the combination of Rockwell and Powers does not render any of the claims obvious.

Brown also does not disclose a defibrillator that allows review on the defibrillator itself of previously recorded ECG history. In fact, Brown does not disclose a defibrillator at all. The Examiner states that Brown "teaches that it is known to display multiple ECG signals, both real time and delayed, on the same screen," citing column 1 lines 9-19 (Office Action at page 6). The Applicants respectfully traverse this interpretation of Brown. As explained more fully at column 9 lines 7-14, Brown discloses displaying different types of patient data (ECG data, blood pressure waveforms, respiratory waveforms, and vital signs) rather than simultaneous display of recorded and current ECG data. Thus, the combination of Rockwell and Brown does not render any of the claims obvious.

In view of the foregoing, all of the Examiner's rejections under 35 U.S.C. § 103 to claims 13, 15, 16, and 18 are believed to be overcome.

#### Other Cited Art

The Examiner made of record but did not rely upon U.S. Patent Nos. 5,785,043 to Cyrus et al. and 5,549,115 to Morgan et al. Neither of these references discloses a defibrillator having an incident review mode wherein a user can review on the defibrillator itself previously recorded ECG data.

#### Additional Fees

The Commissioner is hereby authorized to charge any insufficient or credit any overpayment associated with this application to Deposit Account No. 19-5127 (ref. 19200.0031). A duplicate of this authorization is attached for the Finance Branch.

Conclusion:

Claims 1-28 remain pending in the application. Claims 1, 6, 8, 10, 11, 15, 16, and 19 have been amended. In view of the foregoing amendments and remarks, all of the Examiner's rejections to the claims are believed to be overcome. The Applicants respectfully request reconsideration and issuance of a Notice of Allowance for all claims. Should the Examiner feel further communication would help prosecution, she is urged to call the undersigned at the telephone number provided below.

Respectfully Submitted,



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## Marked-Up Copy of the Amended Claims

1. (Amended) A method of reviewing incident data on an external defibrillator having a screen, comprising:

deploying the defibrillator for use in an emergency, wherein the defibrillator is attached to a patient;

5 monitoring ECG data from the patient;

recording the monitored ECG data in memory; and

activating an incident review mode in which the recorded ECG data is displayed on the defibrillator screen.

6. (Amended) The method of claim 2 wherein the replaying step further comprises replaying [the] audible data recorded into memory during the recording step.

8. (Amended) The method of claim 7 [6] wherein the user selects from the group consisting of: ECG data, audible data, and a combination of ECG and audible data.

10. (Amended) The method of claim 2 [1] wherein the replaying step is activated by the user depressing soft keys.

11. (Amended) The method of claim 2 [1] wherein the replaying step is activated by the user depressing a combination of soft keys.

15. (Amended) The method of claim 2 wherein the replaying is optional and the replaying option is presented to the user when the defibrillator [instrument] is turned off.

16. (Amended) The method of claim 2 [1] wherein the replaying is optional and  
the replaying option is presented to the user when a [the] battery is inserted into the  
defibrillator [device].

19. (Amended) An external defibrillator comprising:

a controller<sub>1</sub>;

an energy delivery system operable by the controller to deliver an electrical  
shock from an energy source to an electrode interface;

5 memory for recording incident data;

a screen;

an incident review activator; and

an incident review output comprising a visual image generator, wherein the  
incident review output retrieves incident data from memory upon activation of the

10 incident review activator by the user and displays the retrieved incident data on the  
defibrillator screen.